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| APPLICATION NO.                   | FILING DATE                | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/574,687                        | 04/05/2006                 | Ikuo Morita          | Q94143              | 3712             |
| 23373<br>SUGHRUE MI               | 7590 07/31/200<br>ON, PLLC | EXAMINER             |                     |                  |
| 2100 PENNSYLVANIA AVENUE, N.W.    |                            |                      | KIM, TAEYOON        |                  |
| SUITE 800<br>WASHINGTON, DC 20037 |                            |                      | ART UNIT            | PAPER NUMBER     |
|                                   |                            |                      | 1651                |                  |
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|                                   |                            |                      | 07/31/2008          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 10/574,687                                                                                                                                                         | MORITA ET AL.                                                              |  |  |  |
| Office Action Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Examiner                                                                                                                                                           | Art Unit                                                                   |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Taeyoon Kim                                                                                                                                                        | 1651                                                                       |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | ears on the cover sheet with the c                                                                                                                                 | orrespondence address                                                      |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period v  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |
| Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                    |                                                                            |  |  |  |
| Responsive to communication(s) filed on 12 Ju     This action is <b>FINAL</b> . 2b)☑ This     Since this application is in condition for allowar closed in accordance with the practice under E                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | action is non-final.<br>nce except for formal matters, pro                                                                                                         |                                                                            |  |  |  |
| Disposition of Claims                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                    |                                                                            |  |  |  |
| 4) ☐ Claim(s) 1-17 is/are pending in the application.  4a) Of the above claim(s) 10-17 is/are withdraw  5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 1-9 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or  Application Papers  9) ☐ The specification is objected to by the Examine  10) ☐ The drawing(s) filed on 05 April 2006 is/are: a)  Applicant may not request that any objection to the second content of the second | n from consideration. r election requirement. r. ⊠ accepted or b)□ objected to l                                                                                   | -                                                                          |  |  |  |
| Replacement drawing sheet(s) including the correct                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                    |                                                                            |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                    |                                                                            |  |  |  |
| Priority under 35 U.S.C. § 119                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                    |                                                                            |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                    |                                                                            |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 4/5/06, 7/2/07,10/19/07, 12/26/07, 6/12/08                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:                                                                                      | nte                                                                        |  |  |  |



Application No.

# **DETAILED ACTION**

Claims 1-17 are pending.

#### Election/Restrictions

Applicant's election without traverse of Group I (claims 1-9) in the reply filed on 6/12/2008 is acknowledged.

Claims 10-17 have been withdrawn from consideration as being drawn to nonelected subject matter. Claims 1-9 have been considered on the merits.

# Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "good" in claim 1 is a relative term which renders the claim indefinite.

The term "good" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is vague how much of adhesiveness can be considered to be "good".

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelles et al. (US 2002/0095219) in light of Sigma-Aldrich (2008), Tarone et al. (1982) and Taguenang et al. (2006).

Nelles et al. teach a method of growing cells on a surface having a pattern of cell-growth promoting molecules and/or cell-growth inhibiting molecules attached thereon (para. 10), and the cell-growth promoting molecules include extracellular matrix proteins (laminin and fibronectin), poly-L-lysine and poly-ornithine (para. 18).

Since the cell-growth promoting molecules of Nelles et al. is well known in the art as cell adhesion molecules, it is an inherent property of the molecules providing cell adhesiveness. As a support, Tarone et al. teach that fibronectin (ECM molecule) has cell adhesive property (see abstract), and a webpage for Sigma-Aldrich describes that polyamino acids such as polylysine and polyornithine facilitate the attachment of cells and proteins to solid surfaces

(www.sigmaaldrich.com/catalog/search/TablePage/17856631).

Nelles et al. also teach a transfer step to transfer cells on cell-growth promoting surface to another substrate by lifting a matrix including the pattern of cells from the prepatterned surface and contacting the pattern of cells with the second surface (para. 19-28). Nelles et al. also teach that the pattern of cells used in one device can be transferred into sterile condition and then be returned to the incubator for a further period of culture (par. 52). Nelles et al. teach the second surface can be tissues,

implants or transplants, thus a biomaterial (par. 31). The pattern of Nelles et al. includes linear regions (see Table 1).

With regard to the limitation of water contact angles being between 10° and 40°, this limitation is not an active method step required for the method claimed in the instant invention, rather it is a property description of the cell adhesiveness region.

Nevertheless, it is well known in the art that a water contact angle of poly-L-lysine is within the range of claimed contact angle as supported by Taguenang et al. (Fig. 3). Figure 3 of Taguenang et al. teaches that polylysine film surface has a contact angle of ~36° (with no UV irradiation).

Thus, the reference anticipates the claimed subject matter.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelles et al. (supra) in view of Kobayashi et al. (US 6,294,313) and Georger et al. (US 5,324,591).

Nelles et al. teach the limitation of claims 1, 2, 7 and 8, and thus render the claims obvious (see above).

Nelles et al. do not teach that the cell adhesiveness variation material being varied by the action of a photocatalyst along with energy irradiation.

Kobayashi et al. teach a substrate having a layer comprising a photocatalyst and a material having varying wettability through the action of photocatalyst upon patternwise exposure to light (see abstract and Figure 1).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to replace the substrate of Nelles et al. with the substrate of Kobayashi et al.

The skilled artisan would have been motivated to make such a modification because it is well known in the art to utilize photolithography for forming a high definition pattern and the pattern-formed substrate has been utilized for cell culture according to Georger et al. (abstract). Furthermore, the material utilized by Kobayashi et al. is organopolysiloxane prepared from a composition containing silane, which is the same material of Georger et al. (silane film) utilized for cell adhesion. Still further, Nelles et al. teach that other techniques for attaching and patterning biomolecules including siloxane

(par. 6). Therefore, a person of ordinary skill in the art would recognize that the wettability varying layer of siloxane/silane substrate of Kobayashi et al. is suitable alternative for cell adhesiveness and patterning purpose to replace the cell growth promoting surface of Nelles et al.

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M.P.E.P. §2144.07 states "The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945) (Claims to a printing ink comprising a solvent having the vapor pressure characteristics of butyl carbitol so that the ink would not dry at room temperature but would dry quickly upon heating were held invalid over a reference teaching a printing ink made with a different solvent that was nonvolatile at room temperature but highly volatile when heated in view of an article which taught the desired boiling point and vapor pressure characteristics of a solvent for printing inks and a catalog teaching the boiling point and vapor pressure characteristics of butyl carbitol. "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301.)".

Kobayashi et al. also teach that the surface having high critical surface tension would have the wettability in terms of contact angle with water being not more than 40° (col. 28, lines 23-27).

With regard to the limitation in claim 9 of the widths and the distance (space widths between lines), the references do not particularly teach the specific limitations. However, the specific sizes of each line formed on the substrate and the distance

between such lines are considered to be result-effective variables. As such, the variables would be routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by those references. Generally, differences in sizes and distances will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); >see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); \*\* In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the :references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d Art Unit: 1651

1362 (Fed. Cir. 1997). Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Although Nelles et al. in view of Kobayashi et al. and Georger et al. do not particularly teach the cells being used in the method is vascular endothelial cells, since the method can be applicable to any type of cells, and further Georger et al. teach the use of pattern of cell adhesion promoters to promote the adhesion of endothelial cells, it would have been obvious to a person of ordinary skill in the art to try endothelial cells in the method of Nelles et al. in view of Kobayashi et al. and Georger et al.

The Supreme Court recently states in KSR v. Teleflex (550 US82 USPQ2d 1385, 2007) "The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." Id., at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103." See also M.P.E.P. §2141.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

### Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/ Primary Examiner, Art Unit 1651

Taeyoon Kim AU-1651